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10/726,557

12/04/2003

Leila Toumi

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08/20/2007

OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.

1940 DUKE STREET

ALEXANDRIA, VA 22314

EXAMINER

SILVERMAN, ERIC E

ART UNIT

PAPER NUMBER

1615

NOTIFICATION DATE

DELIVERY MODE

08/20/2007

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentdocket@oblon.com

oblonpat@oblon.com

jgardner@oblon.com

Office Action Summary

Application No.

10/726,557

Applicant(s)

TOUMI ET AL.

Examiner

Eric E. Silverman, PhD

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) 12-14 and 18-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 15-17 and 23-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 6-4-04
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: ____

DETAILED ACTION

Claims 1 – 26 are pending in this action.

Election/Restrictions

Applicant's election with traverse of Group I, claims 1 – 17 and 23 – 26 and the species of phenylpropylsilsesquioxane in the replies filed on 4/3/2007 and 6/29/2007 is acknowledged. The traversal is on the ground(s) that there is no burden to search the various Groups and Species. This is not found persuasive because all of the Groups are classified in different classes or subclasses, which constitutes a *prime facie* showing of search burden. The species require a burden of search because search of each species would require different search queries and would require looking at different types of technical literature.

The requirement is still deemed proper and is therefore made **FINAL**.

Claims 18 – 22 are withdrawn as being directed to a non-elected Group. Claims 12 – 14 are withdrawn as being drawn to non-elected species. Claims 1 – 11 and 15 – 17 are treated on the merits in this action.

Claim Rejections - 35 USC § 112

Claims 1 – 11, 15 – 17, and 23 – 26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the combination of agents and polymer (phenylpropylsilsesquioxane) shown in the examples, does not reasonably provide enablement for any other polymer, or combinations of other agents with this polymer. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention

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commensurate in scope with these claims. Enablement is found lacking when a person of ordinary skill in the art cannot make or use (in this case use) the invention without undue experimentation. Undue experimentation is determined using the factors enumerated in MPEP 2164.01(a). All of these factors have been considered, and the most relevant are discussed below.

- *The breadth of the claims.* The claims are drawn to particles having a synthetic polymer with an aryl group and a glass transition temperature greater than 45 C in and an active agent with a molecular weight less than 1,000, the active having at least one aromatic, carbocyclic, heterocyclic, monocyclic, or fused polycyclic group. In their broadest sense, the claims read on almost any polymer with the requisite aryl group, which includes polymers with quite a diverse set of structural properties, for example, Kevlar, polystyrene, polyphenylsiloxanes, polystyrene sulfonate, and polyphenylpropylsilsesquioxane. There are no limitations regarding the molecular weight of the polymer, which may therefore be from about a hundred to over a million Daltons. No limitation regarding the type of excipients that may be added is present.
- *The nature of the invention.* Applicants have made particles comprising active agents and phenylpropylsilsesquioxane polymer. These agents allegedly are useful for applications where active agents having a molecular weight less than 1,000 are desired, and it is further desired

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that the active agents do not leach out of the particle, nor do any materials that may degrade the active agent leach into the particle.

- *The state of the prior art.* The art does not recognize the equivalence between all polymers having aryl groups, nor does it recognize the equivalence (as far as degradation and leaching). With regard to leaching, the art recognizes that rate of movement of a molecule in a condensed phase is related to the inverse square of its hydrodynamic volume, which is in turn related to the molecules molecular weight.
- *The level of one of ordinary skill.* The relevant art is chemistry. The person of ordinary skill in the art has a bachelors degree, or the equivalent thereof (see C&EN July 24, 2006, which shows that bachelors degrees in chemistry are awarded about 5 times more frequently than PhD degrees). This is a fair estimate of the person of skill, since many artisans have completed less than a bachelors degree (for example, a technical degree). Considering this level of education and technical experience, the artisan has the ability to follow standard operating procedures, but does not have the skill to optimize those procedures. The artisan recognizes the names and structures of various materials used in the art, but does not know how to substitute one material for another without explicit instruction. The artisan knows how to take routine measurements to determine the properties of materials, but is

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unable to determine, without explicit instruction, other materials that are likely to have the same or similar properties to those that are measured.

- *The level of predictability in the art.* The art of protecting materials from degradation is quite unpredictable. There are a wide variety of means by which materials may degrade, including oxidation by air and similar materials, epimerization, reaction with water, reaction with impurities, photodegradation, thermal degradation, and so forth. These mechanisms may act individually or in combination. The applicability of one or more of these degradation mechanisms is not clear *a priori*.

Further, even when degradation of an active agent is noted, it is often not easy to determine what degrading mechanism is responsible.

- *The amount of direction provided by the inventor and the existence of working examples.* The inventor only alleges that any polymer having aryl groups and a Tg over 45 C will solve the problem of degradation and leaching of actives from particles. The specification provides no nexus between these polymer properties and the mechanism by which the problem is allegedly solved. The working examples show the making of particles with phenylpropylsilsesquioxane polymer, but do not actually show how to use the particles in order to obtain the stated effects (that is, to use the particles such that leaching and degradation is prevented). Further, the specification gives no guidelines as to how to manipulate the particles and retain or achieve the desired benefits. What solvents or

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media may the particles be dissolved or dispersed in to prevent leaching and degradation? If the particles are to be tableted, what compression forces may be used? At what heat (and for how long) is thermal degradation prevented? And how do the answers to these questions changed when the active agent or polymer are varied? These are just some of the questions which are not answered by the instant disclosure.

- *The quantity of experimentation needed to use the invention based on the content of the disclosure.* In order to use the invention, the artisan would first have to determine, for each active agent, what degradation mechanisms are likely to cause degradation. The artisan would then have to determine what polymer with aryl groups would serve to prevent these mechanisms. Subsequently, the artisan would have to determine how the particle could be used so that no degradation or leaching actually occurs.

Since the specification does not give any useful guidance on how to go about the required experimentation, and because the art is unpredictable and the skill level is fairly low, the amount of experimentation needed to use the invention is clearly undue. As such, the invention is not fully enabled by the disclosure.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 – 9, 15, 16 and 23 – 26 are rejected under 35 U.S.C. 102(b) as being anticipated by US 5,242,689 to Yoshihara et al.

This rejection is made based on the claimed components of the composition.

The claims are drawn to particles containing at least one active principle comprising one or more aromatic or cyclic functional groups with a molecular weight equal or less than 1,000 and at least one synthetic polymer having aryl groups with a Tg of 45 C or greater. Dependent claims include limitations as to the nature of the active principle (molecular weight equal or less than 500, having ionized or ionizable groups, being a specific type of agent, and so forth), the nature of the polymer (being non-ionic, having phenylene groups as the aryl groups, and so forth), to the weight ratio of the polymer and active, and to the nature and size of the particles. Note that claims 16 and 17 are product by process claims wherein the process is only afforded patentable weight insofar as it causes some patentable distinction in the product.

Yoshihara teaches a cosmetic composition of polymer particles coated with a pyrrole-based pigment (synthesis examples 1 and 2). Although the structure of the pigment is not well defined, it is believed to meet the molecular weight requirements of instant claims, and further, is ionizable on the basis of it containing pyrrole, which is an ionizable heterocyclic. The polymer may be polystyrene in a preferred embodiment (col. 2, lines 37 – 60). The particle diameter is between 0.01 and 200 microns, which is squarely within the range of instant claims 15 and 16. Polystyrene is nonionic as required by claim 9. The active dye is a hair dye, as required by claims 7 – 8. The weight ratio of the active to the polymer (see examples) is within the ranges of instant claims.

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Conclusion

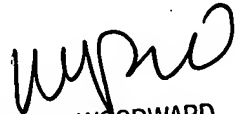
No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric E. Silverman, PhD
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MICHAEL P. WOODWARD
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600